

HEMOSTATIC SYSTEM FOR BODY CAVITIES

5 This application is a continuation-in-part of U.S. Patent Application Serial No. 09/927,864 filed August 10, 2001, which in turn is a continuation-in-part of U.S. Patent Application Serial No. 09/406,166 filed September 27, 1999, which in turn is a continuation-in-part of U.S. Patent Application Serial No. 09/057,414, filed on April 8, 1998.

TECHNICAL FIELD

10 This invention relates generally to medical devices and methods of use, and more specifically, to materials, apparatus, and methods for facilitating hemostasis within a body cavity or passageway.

BACKGROUND OF THE INVENTION

15 Nasal passageways, for example, are often susceptible to uncontrolled bleeding caused by various forms of trauma, disease or cellular dysfunction. Methods and devices for controlling, limiting or stopping such bleeding would be useful in a variety of situations, ranging from emergency room care to long term care.

Bleeding is typical after nasal related surgeries or procedures, and epistaxis related to a patient's nasal passageway can be difficult to control. Hemostatic agents, such as carboxymethyl cellulose (CMC) and woven knit or matted fabrics thereof, are known for use in the control of bleeding, such as post-trauma and post-surgical
5 bleeding. CMC is defined as a polycarboxylmethyl ether of cellulose or the sodium salt thereof. It is sometimes referred to as cellulose ether, carboxymethylcellulose, or sodium carmellose. Insertion, application, and subsequent removal of these materials, however, can be difficult in small body passageways, such as nasal cavities.

SUMMARY OF THE INVENTION

The present invention comprises methods and devices for the control of bleeding from an inner wall of a body passageway or cavity. Briefly, the invention comprises an inflatable, expandable balloon, usually covered by a hemostatic shroud, which is inserted into a body cavity, such as a nasal passageway. The shroud is
10 composed of a hemostatic agent; that is, the shroud acts to facilitate or enhance blood clot formation. The balloon component of the present invention is expanded, or inflated, within the cavity in order to press the shroud against the site of bleeding, thereby allowing it to absorb blood and facilitate hemostasis. In specific
15 embodiments, the shroud is composed of a woven or knitted fabric of a hemostatic fiber (such as carboxymethylcellulose) or a reinforced hemostatic fiber. Optionally, this shroud may include an "extension" or "tail" fiber, which upon balloon deflation and removal, facilitates the later removal of the shroud which has been intentionally left in vivo.
20

The device construction, particularly the balloon construction, may vary according to the particular body cavity. Although a range of different materials can be used for any of the embodiments, there are particular materials which work better than others, depending upon the particular application. For a nasal application, one
5 embodiment includes an inflatable balloon made from a relatively inelastic material.

A particular embodiment of the invention comprises a device for insertion of a shrouded balloon into a nasal passageway by a catheter configured such that the balloon encircles the catheter tube. The lumen of the catheter tube thereby serves as a passageway for breathing. The inflated balloon compresses the shroud against the
10 bleeding nasal wall, thereby facilitating or enhancing hemostasis. The balloon is deflatable such that, upon balloon deflation, the shroud may be left in place on the cavity wall and may be removed at a later time, such as by an attached extension on the shroud.

In another embodiment, there is no central lumen. This gives the catheter a
15 much smaller overall diameter. In patients with small nasal cavities, the lack of the breathing passageway is more than compensated for by the small profile which is far less traumatic and painful during insertion.

The shroud used in the present invention may comprise a woven or knitted fabric combining hemostatic (e.g., carboxymethylcellulose (CMC)) fibers with
20 reinforcing fibers. Alternatively, the shroud may be just a hemostatic agent disposed on the balloon in a film-like covering.

BRIEF DESCRIPTION OF DRAWINGS

For a better understanding of the present invention, reference may be made to the detailed description which follows, taken in conjunction with the drawings, in which:

5 Figure 1 is a side view of a component adapted for insertion in a nasal passageway;

Figure 2 is a side view of the component shown in Figure 1 covered with a hemostatic shroud;

Figure 3a is a cross-sectional view of a device as shown in Figs. 1 and 2;

10 Figure 3b is a cross-sectional view of a device as shown in Figs. 1 and 2;

Figure 4 is a schematic view of a knitted fabric structure useful in the present invention;

Figure 5 illustrates another embodiment of the invention which uses a pressure-indicating pilot balloon;

15 Figure 6 illustrates a close-up, cross-sectional view of the inflatable balloon and shroud in accordance with the present invention;

Figure 7 illustrates the same embodiment as illustrated in Figure 5 with the pilot balloon deflated and turned 90°;

Figure 8 illustrates the same embodiment as illustrated in Fig. 7 but with the system inflated;

Figure 9 is a partial cross-sectional view of a device according to one embodiment of the present invention using a clamp ring;

5 Figure 10 is a partial cross-sectional view of the device of Fig. 9 having a balloon disposed between the central tube and the shroud;

Figure 11 is a side view of one embodiment of the present invention where the balloon is rolled around a central tube;

FIG. 10

10 Figure 12a is a cross-sectional view of the balloon rolled around the central tube;

Figure 12b is a cross-sectional view of the balloon unrolled and deflated around the central tube;

Figure 12c is a cross-sectional view of the balloon inflated around the central tube;

15 Figure 13 is a cross-sectional view of the balloon rolled around the central tube, with a shroud disposed therearound in accordance with the present invention;

Figure 14 is the cross-sectional view of Figure 13 but with the system inflated;

Figure 15 is a side-view of the device shown in Fig. 11 but without the central tube;

Figures 16a-16e show the steps for forming a device in accordance with the present invention using a tube tool;

Figures 17a and 17b show a deflation hole in a central tube in accordance with one embodiment of the present invention;

5 Figure 18 shows a side, partial cross-sectional view of a central tube without a deflation hole during deflation;

Figure 19 is a cross-sectional view of the device with an inflation/deflation hole; and

10 Figure 20 shows a device in accordance with the present invention where the inflation tube is not coaxial with a breathing lumen, and the inflation tube has an inflation/deflation hole.

DETAILED DESCRIPTION OF THE INVENTION

15 The present invention comprises systems, devices, and methods for the control of bleeding in body cavities, such as nasal passageways. Generally, the terms “cavity” and “passageway” may include any bodily cavity, recess, passageway, etc., other than a blood vessel or other component of the vasculature system, and it encompasses those which are healthy and normal as well as those which are abnormal and/or pathological (meaning, diseased or unhealthy).

20 The term “hemostatic” agent (or material) refers to any agent or material that is capable of arresting, stemming, or preventing bleeding by means other than

inducing tissue growth alone. In other words, something other than tissue growth is at least partially responsible for retarding or preventing bleeding. Preferably, the agent or material will be one that enhances blot clot formation. It will, of course, be appreciated that the agent or material may have the beneficial property of inducing tissue growth in addition to retarding or preventing bleeding. Examples of preferred hemostatic agents which enhance blood coagulation include carboxymethylcellulose (CMC), oxidized cellulose, calcium alginate, gelatine, or collagen. CMC can be purchased from Acordis Special Fibres, PO Box 111, 101 Lockhurst Land, Coventry, England, CV6 5RS. Oxidized cellulose such as Tabotamp TM, which is sold by Johnson & Johnson, New Brunswick, NJ, U.S. A., is another example of a hemostatic agent. Combinations of different hemostatic agents or materials may be used within the scope of the invention.

The hemostatic agent may be a part of an expansible shroud or may make up the shroud itself. In this later case, the hemostatic agent is either a film or fabric comprised of the hemostatic agent. In the former case, the hemostatic agent is combined with another material, such as a reinforcing fiber material. Typically, the hemostatic agent-containing shroud covers an expansible device such as a balloon. The shroud may be in the form of an expandable tube or in the form of an expandable sheet. In specific embodiments disclosed, the preferred hemostatic agent is a fibrous CMC, which is hemostatic and so will cause blood to clot while at the same time absorbing any exudate. A fabric of CMC fiber is preferred because, aside from its hemostatic properties, it swells and forms a gel, absorbing many times its own weight in fluid when it contacts water (or blood or exudate). Because the CMC material is so hygroscopic, it does not dry into the clotted blood, and therefore can be removed easily without tearing the clot and causing re-bleeding.

Other hemostatic agents which may be used should have absorptive and hemostatic properties similar to those of CMC. In one embodiment, the hemostatic agent fibers are woven or knitted together with reinforcing fibers, such as continuous multifilament polyester or nylon. Such a knitted fabric is illustrated in Fig. 4, and is more fully described and claimed in separate patent applications (U.S. Serial Nos. 09/406,490 filed September 27, 1999, pending; and 09/612,038 filed July 7, 2000, pending; both of which are incorporated by reference herein). The use of reinforcing fibers provides increased strength to the shroud. This increased strength is important for successful removal of a blood-soaked fabric, where the CMC or gellable material has formed a gel and therefore lost much of its strength.

Examples of some other hemostatic materials include oxidized cellulose, which is conventionally used in knitted form as a hemostatic agent during surgery, and calcium alginate, which is a textile fiber derived from seaweed and is also commonly used as a wound dressing. Furthermore, there are other polysaccharides which are available with similar chemistry and properties to CMC. For purposes of the present invention, the essential properties of the hemostatic material are the ability to absorb large quantities of liquid without becoming enmeshed in the clotted blood. The material must be non-toxic and biocompatible.

Preferably, the shroud is provided in the form of a woven or knitted, especially a weft knitted, textile fabric in which is incorporated the hemostatic material, and which envelops the balloon. The woven or knitted textile material may be permanently or releasably fixed to the balloon.

In some embodiments, particularly those used in nasal applications, the balloon will be made of a relatively inelastic material, such as polyurethane or PVC.

Alternatively, for other uses and embodiments, the balloon can be made from an

elastomeric material, such as a thin silicone polymer. These balloons can be made by methods known to those skilled in the art, such as by dip molding. As noted above, it is generally desired in nasal applications that the balloon have a fixed volume and be made of an inelastic material. In such a case, the balloon is effectively a bag that can be filled or emptied with an inflation medium. A fixed volume, inflatable, inelastic balloon does not require the inflating medium to first stretch the elastic material of the balloon (as would be the case where the balloon is made from an elastomeric material). All inflation medium pressure is used to fill the cavity. This is essential when the device is used with a pilot balloon to give a tactile feedback of the pressure inside the catheter balloon. With an inelastic, fixed volume balloon, the tactile feedback is truly representative of the pressure applied to the inner surface of the nasal cavity.

For particular non-nasal applications, an elastic material such as silicone rubber can be used for the balloon. Such a balloon may be inflated with a liquid medium such as water or saline solution and the volume controlled by monitoring the volume of fluid inserted. Silicone rubber has the property of being permeable to air but not to water or saline solution.

One specific embodiment of the present invention which is designed for insertion within a nasal passageway is depicted in Figs. 1-3. As shown there, a balloon catheter 50 consists of a soft flexible central tube 41, with a long non-elastomeric balloon 48 adhered to the outside wall of central tube 41 along the end sections 49 of balloon 48. The wall of central tube 41 includes an inflation lumen 51 (inflation passageway) which is in communication, through a thin tube 42, with a valve and luer 43 at one end and an inflation port 52 at the other end. The valve 43 is opened by the tip of a standard syringe by which the balloon 48 may be inflated or

deflated at will. Tube 41 includes a central breathing lumen 53 which serves as an air passage for breathing.

In a specific exemplary embodiment, central tube 41 has an approximate outside diameter of 10mm, and an inside diameter of 4-5mm. The active length is typically between 40 and 100mm, although shorter or longer lengths may be required for special applications. One end of catheter 46 may have a reduction in the outer diameter in order to provide a shoulder 40. This shoulder is used to locate and maintain the position of an outer hemostatic shroud, (seen in Fig. 2 and discussed in more detail below), during insertion of the device of Fig. 2 into a nasal passageway. In another method of construction the glued neck of the balloon supplies the shoulder and in yet another construction method no shoulder is used and the fabric is retained by a ring and glue or merely by glue alone. Catheter tube 41 typically is comprised of a silicone elastomer or PVC. In the embodiment of the present invention for use in a nasal passageway, the balloon is typically of fixed volume with an expanded diameter of approximately 25mm and is expanded by inflation with air.

Fig. 2 illustrates the balloon catheter component of Fig. 1 covered by a hemostatic shroud 44 which envelopes a portion of catheter tube 41. Hemostatic shroud 44 can be a soft knitted or woven fabric tube made from a hemostatic material with a high absorption ability. The shroud material is discussed in more detail below. Shroud 44 is draped around the balloon catheter 50 and is positioned by a sewn ring or ligature 45, which locates over shoulder 40 at the distal end 46 of the balloon catheter. The "ring over shoulder" mounting allows shroud 44 to be located precisely over balloon 48 when the device is inserted into the nasal cavity, but permits balloon 48 to be released from shroud 44 by simply withdrawing the catheter. Other methods of locating the shroud may also be used, such as a glued grommet, a welded ring, or

by actually shaping the knitted shroud for retention on the balloon. The fabric shroud is highly elastic and deformable which allows it to stretch and/or deform as the balloon is inflated. An extension tail 47 to shroud 44 may be provided as a means to remove the hemostatic element separately after balloon 48 has been removed.

5 Fig. 3a shows a cross section, in the plane A-A, of nasal catheter 50 of Fig. 1 with hemostatic shroud 44 shown disposed thereon. As shown in Fig.3, balloon 48 is covered by hemostatic shroud 44, encircling central tube 41 and the non-adhered underside thereof is in communication with inflation port 52.

10 In service, balloon 48 is inflated by filling material, typically compressed air, from a syringe in communication with valve 43 and the inflation lumen 42 which terminates in port 52 at the inner surface of balloon 48 between the ends of the balloon which are adhered at tube surface areas 49.

15 Fig. 4 illustrates a schematic view of a preferred fabric for the hemostatic shroud. Specifically, spun CMC yarn 60 is knitted in parallel with a polyester reinforcing yarn 61, as more specifically described in the aforementioned U.S. patent applications incorporated by reference. In this preferred embodiment, the knitted fabric tube is manufactured first by knitting a tube from Lyocell yarn in combination with the reinforcing filament. Lyocell is the generic name for solvent spun cellulose fiber. A brand thereof, "Tencel," (a registered trademark), is available from
20 Accordis Fibres, Coventry UK. Lyocell is produced from the natural cellulose in wood pulp by dissolving the wood pulp in a solvent and then extruding the product through a die called a spinneret. The solvent is then evaporated therefrom, thereby leaving a fiber which is composed of pure cellulose. After knitting, the fabric tube is subjected to a sodium reactant, according to known techniques, which serves to
25 convert the pure cellulose at least partially, into sodium carboxymethylcellulose. The

chemical conversion process is similar to that used to make carboxymethylcellulose sodium USP, except that the raw cellulose is in fiber form rather than the more normal powder form. Other cellulosic raw materials can also be used such as cotton or viscose rayon.

5 One use of the hemostatic nasal device of Figs. 1-3 involves inserting into a nasal cavity the shroud-covered balloon catheter 50 illustrated in Fig. 2. Balloon 48 is then inflated. Because the shroud is deformable, it is able to expand and not limit the balloon in its ability to inflate and fill the cavity. The hemostatic fabric is pressed against the vessel wall and into contact with the blood. On contact with blood, the
10 hemostatic shroud, typically CMC (or other similar material) is pressed against the cavity wall and swells to form a gel. It absorbs blood and exudate while its hemostatic properties facilitate and enhance blood clot formation. The lumen of the large (catheter) tube provides for normal breathing, while the inflated balloon provides an anchor for the device. After hemostasis is achieved, the balloon 48 is
15 deflated, and then the catheter is removed. The soft gel nature of the wet fabric shroud ensures that the device does not adhere to the clot. In one embodiment the balloon and tube only are removed and the gelled fabric is left in situ.

Where the gelled fabric alone has been left in situ, the fabric may be removed at any later time by means of the withdrawal string or "tail" 47. Since the
20 hygroscopic nature of the hemostatic fabric prevents the material from sticking to the clotted blood, removal is simple and with minimal chance of restarting the bleeding process.

In an alternative embodiment, the outer surface of the balloon itself is coated with an agent that facilitates blood coagulation. In such an embodiment, the shroud
25 does not comprise a fabric of any kind, but is the hemostatic agent itself, provided in

the form of a flexible film that coats the outer surface of the balloon. Examples of coating material include gelatin and collagen, but the invention is not limited to these. Such an embodiment is shown in Fig. 3b, which is identical to Fig. 3a except that the shroud 70 is comprised only of a film of hemostatic agent (no fabric). In slight distinction, Fig. 3a shows shroud 44 which is comprised, as described above, of a soft knitted or woven fabric made from a hemostatic material with a high absorption ability.

Pilot Balloon Tactile Pressure Indicator

In another embodiment, the device of this invention may include a tactile pressure-indicating pilot balloon in fluid communication with the balloon by which pressure is exerted on the hemostatic shroud. In such an embodiment, both the shroud compressing balloon and the pilot balloon are expandable. Preferably, both balloons are inflatable but made of a non-stretchable material. In this embodiment, the "balloons" are really more like bags or plastic sacks which receive an inflation medium such as air. Once the balloon is fully inflated, its volume no longer changes because the material of which it is made does not stretch. In use the balloon will typically not be inflated to its maximum volume because the cavity into which the balloon is inflated will preferably be smaller than the theoretical maximum volume of the balloon. This is because the maximum volume and dimensions of the balloon are typically chosen to be larger than the cavity in order that the balloon always has the capacity to fill the cavity. In this way, the hemostatic shroud, which surrounds the balloon, is pressed against the complete inner surface of the cavity.

Such a pilot balloon may be disposed at the end of the inflation tube opposite the inflatable balloon of a nasal device as shown in Fig. 5. In this embodiment, pilot balloon 190 is connected to first inflatable balloon 191 via inflation tube 195. Thus, the external tactile pressure sensing pilot balloon 190 does not enter the passageway but allows the user to feel the pressure (usually by grasping the pilot between thumb and finger) within the system as the first inflatable balloon 191 is inflated. In this embodiment, the pilot balloon 190 inflates along with inflatable balloon 190 during placement of hemostatic shroud 196 because the two balloons are in fluid communication with each other. Thus, during placement, the doctor is able to touch the pilot balloon and feel the pressure increase as the system inflates. As discussed above, this may be particularly important in nasal passageway applications, for example, because too little inflation pressure may result in a lack of blood flow stoppage, and too great an inflation pressure may damage the passageway. Thus, through a careful tactile determination of system pressure during inflation and placement of the hemostatic fabric, proper and effective use of the device is insured.

In order for the tactile pressure sensing pilot balloon to give a more accurate indication of the pressure inside the nasal cavity, it is preferred that the first inflatable balloon (catheter balloon) be non-stretchable. In accordance with this aspect of the invention, the balloon is made of a relatively inelastic material (such as polyurethane or PVC) in order to have the ability of completely filling a cavity without any energy being used to stretch the wall of the balloon. In such a case, the balloon is effectively a bag that can be filled or emptied with an inflation medium. The inflatable, non-stretchable balloon does not require the inflating medium to first stretch the elastic material of the balloon (as would be the case where the balloon is made from an elastomeric material). This is preferred when the device is used with a pilot balloon to give a tactile feedback of the pressure inside the catheter balloon. With a non-

stretchable balloon, the tactile feedback is more representative of the pressure applied to the inner surface of the nasal cavity.

Fig. 5 also illustrates hemostatic shroud 196 disposed on first inflatable balloon 191. As discussed above, various means for introducing air or other suitable pressurizing fluid into the system can be used. Fig. 5 shows a Luer slip valve 197 attached to one end of a pilot balloon 190 the opposite end of which is connected via inflation tube 195. Such slip valves are known to those skilled in the art to provide the introduction of an inflating medium, typically air, into the system. Also shown in Fig. 5 is fabric clamp ring 198 used to hold the hemostatic shroud 196 to the inflation tube and/or base of inflatable balloon 191. In this embodiment, which includes no central tube, inflation tube 195 ends where inflatable balloon 191 and inflation tube 195 connect at clamp ring 198. In the alternative embodiment shown in Fig. 6, an inflation tube 200 actually extends into inflatable balloon 191.

Fig. 6 illustrates a close-up, partially cross sectional view of inflation balloon 191 within hemostatic shroud 196. Within inflation balloon 191 is internal inflation tube 200. Internal inflation tube 200 as shown in Fig. 6 is either an integral extension of an inflation tube 195 as seen in Fig. 5, or is a separate piece of tubing in fluid communication with an inflation tube 195 as seen in Fig. 5. Internal inflation tube 200 is shown as open at its end 205 in Fig. 6.

In Fig. 6, the hemostatic shroud 196 is shown folded back over itself along the length of the inflation balloon 191. In assembling the shroud 196 over the balloon 191, half the fabric length is first placed over the balloon and the excess fabric is given a complete turn (or 360° twist) before inverting the twisted excess fabric over the balloon to give the second layer of fabric. This has the effect of closing the fabric over the distal end of the balloon as shown in Fig. 6.

Fig. 7 illustrates the embodiment shown in Fig. 5 with pilot balloon 190 turned 90° from the view shown in Fig. 5. Fig. 6 is presented to illustrate the deflated pilot balloon which accompanies deflated inflatable balloon 191. After an inflation medium (preferably air) is introduced into the system, the resultant configuration of pilot balloon 190 is shown in Fig. 8. This inflated pilot balloon 190, as shown in Fig. 8, when touched or gripped by the doctor using the device, qualitatively indicates the pressure in the system.

In one embodiment, the pilot balloon as illustrated in Figs. 5-8, has a wall thickness of about 0.09mm (0.0035 inches) and is comprised of polyvinyl chloride (PVC). Typically, the pilot balloon is approximately 0.5 to 2 inches in length.

In its nasal embodiments, the method comprises the steps of inserting into a nasal cavity a first inflatable balloon surrounded at least in part by a hemostatic shroud comprising a gel-forming absorbent composition. The inflatable balloon is then expanded which compresses the shroud against the inner surface of the cavity where bleeding is to be controlled. Where the device includes a pilot balloon, the pressure inside the inflatable balloon is monitored, during expansion of the inflatable balloon and shroud, by touching the pressure-indicating pilot balloon which is in fluid communication with the first inflatable balloon.

Nasal Applications

Soft Tip

When it is desired to use the present invention in a narrow body cavity, such as in a nasal application, several embodiments are particularly advantageous. One such

embodiment includes a soft tip to allow easier insertion into the nasal cavity as compared to a device not having a soft tip. The soft tip allows for less damage and irritation to the wall of the nasal cavity during insertion, particularly where the cavity does not exhibit smooth or straight walls. For this purpose, a soft tip can be formed on the distal end of a shaft which is configured to be inserted into a particular body cavity.

In one such soft-tip embodiment, shown in Fig. 9, central tube 230 is covered along its length by a suitable fabric 232, such as a CMC fabric, or a knitted CMC-reinforcing filament fabric as described above. Fabric clamp ring 234, composed for example of medical grade PVC, is disposed longitudinally on the distal end 235 of central tube 230 and pinches fabric 232 to tube 230. Clamp ring 234 is made from a length of very soft flexible tubing. It is not positioned completely onto tube 230, however, but extends longitudinally beyond distal end 235 of tube 230.

During manufacture of this embodiment, a cylindrical piece of fabric 232 is slipped over central tube 230 and clamp ring 234 is slid over fabric 232 and part way on to central tube 230. Then, fabric 232 is folded back, and inverted, around tube 230 to create a double layer of fabric along tube 230. After fabric 232 is folded, a folded section 236 is created. This folded region 236, draped over the very soft flexible clamp ring 234, forms a soft tip which reduces trauma as the device is inserted into a body passageway.

In one embodiment, glue can be used to set clamp ring 234 into place. The glue would be placed between fabric 232 and tube 230 where the clamp ring overlaps tube 230. A preferred glue is a cyanoacrylate based glue, a more preferred glue being Loctite 4011. Loctite is a registered trademark of Loctite Corporation.

Fig. 10 shows the embodiment of Fig. 9 but with a balloon 240 disposed between shroud 232 and central tube 230. Balloon 240 is attached toward the distal end of central tube 230 by any of a number of means, including the use of glue or heat sealing the balloon directly to central tube 230 at its distal end 241. Means for inflating balloon 240 are not shown in Fig. 10, but are addressed in other parts of this specification.

A second way to achieve the soft tip of the invention is used on the version which does not include a central airway or breathing tube. This involves rolling the balloon around the central tube or rolling the balloon around itself underneath the fabric (See Figure 15). In the former embodiment, a thin-walled balloon is disposed on a central tube and, when deflated, is flattened and rolled around the tube around the same longitudinal axis defined by the central tube, similar to how a roll of paper towels are disposed around a cardboard tube. Fig. 11 shows such an embodiment where balloon 240 is rolled around central tube 230. Balloon 240 is sized so as to extend beyond the distal end of central tube 230. The region of extension 245 provides a soft tip for the device which achieves the above described advantages during placement. Preferably, the balloon is made from a film welding technique to achieve a very thin walled balloon. Typical materials for the balloon include PVC and polyurethane. Any suitable polymer would work, so long as it is easily welded and maintains adequate strength to allow expansion of an inflation medium without breaking.

Film welding techniques (including radio frequency welding) are well known to those skilled in the art and are used in a variety of larger products such as blood bags, intravenous (IV) drug bags, pouches for card or badge protection, etc. Generally, the thinner the material, the better, so long as adequate strength is insured. The preferred

thickness for the balloon thin film material is between 0.03 mm and 0.15 mm. The combination of this very thin walled balloon along with a thin inflation tube and thin fabric allows for a very small diameter device. The smaller the diameter, the easier the device can be inserted into a nasal passageway.

5 Figs. 12a-12c show three cross sections of balloon 240 and central tube 230. Fig. 12a shows the balloon rolled around central tube 230. Fig. 12b shows the balloon 240 unrolled but not fully inflated around central tube 230, and Fig. 12c shows the balloon 240 inflated around central tube 230. Fig. 13 shows the cross section of Fig. 12a with shroud 232 shown disposed around the balloon 240. When
10 central tube 230 receives inflation medium (typically air), the medium passes through a passageway, typically a hole (not shown) in the wall of tube 230 and into the interior of balloon 240. Balloon 240 then expands and unrolls within shroud 232 and expands to cause shroud 232 to contact the inner surface of the body passageway or cavity where bleeding is to be controlled. Fig. 14 shows balloon 240 expanded within
15 shroud 232. Figs. 13 and 14 show the shroud 232 as a two layer shroud, consistent with the embodiment shown in Fig. 10. The shroud could, however, be single layered or have more than two layers.

The balloon rolling does not have to be rolled around a central tube. As described above, no central tube is present in some embodiments. In such a case, the
20 fabric would be disposed around a rolled balloon where the balloon is simply rolled up on itself. An example of this later embodiment is shown in Fig. 15. A tubular connection for introducing inflation media would obviously be included. A forceps or other instrument may be required to deploy such an embodiment.

Twisted Fabric Construction

In another embodiment, the shroud is attached to the inflation lumen at only the proximal end of the device, as shown in Figs. 6 and 16e. Here, shroud 232 is doubled-up, back over itself along the length of central tube 230. In this embodiment, however, and unlike the embodiment shown in Fig. 9, the assembly of shroud 232 over balloon 240 involves the twisting of the fabric at its distal end. Here, half the fabric length is first placed over the balloon and the excess fabric is turned, preferably in a complete turn (or 360° twist) at its distal end before inverting the twisted excess shroud back over the balloon and first layer of shroud to provide the second layer of shroud. This has the effect of closing the shroud over the distal end of the balloon as shown in Fig. 6. In such an embodiment, balloon 240 is only secured to central tube 230 at its proximal end. This allows for the use of only one attachment means for the entire device, such as glue or a clamp ring 257.

The present invention also includes a method for manufacture of a device as represented in Fig. 6. This method, as shown in Figs. 16a - 16e, involves the use of an assembly tool 260 as shown in Fig. 16b. This tool is a relatively thin-walled cylinder and is made from a relatively rigid, or stiff, preferably transparent material.

The method first requires the placement of shroud 232 over the balloon 240 and central tube 230, as shown in Fig. 16a. In the next step, assembly tool 260 is pushed into shroud 232, which shroud is simultaneously stretched around the outside surface of assembly tool 260, as shown schematically in Fig. 16b. Fig. 16c illustrates the third step, which requires rotating assembly tool 260, and shroud 232 along with it. The preferred rotation is 360°, although more rotation would achieve the same purpose. The next step is shown in Fig. 16d, which illustrates the progression of assembly tool 260 toward the proximal end of the device, which causes shroud 232 to

double over on itself, forming a double layer of fabric along the outside surface of balloon 240. Fig. 16e shows the result of this method, after a clamp ring 257 is placed around shroud 232 at the proximal end of the device, thereby securing the fabric in place. Any excess fabric that would extend beyond the clamp ring 257 could then be trimmed from the device.

Glue could also be used with this embodiment. During the step of placing clamp ring 257, a small amount of glue could be injected under the clamp ring at two spots, one each at 180° from the other around the circumference of the inflation tube where clamp ring 257 will be secured. Because the fabric is meshed, in the preferred embodiment, the glue will contact the fabric, the inflation tube, and the inside of the clamp ring, binding all three components together.

This method can also be used to place fabric around a device which has no central inflation lumen, but which has only an inflation balloon attached to the distal end of the inflation tube. Such an embodiment is shown in Fig. 5. In such a case, only the balloon and fabric extend beyond the distal end of the inflation tube.

In some embodiments of the invention, particularly those not including a breathing lumen, there is a risk that upon deflation, the balloon and/or surrounding fabric will be sucked into the passageway by which inflation medium passes from the central tube into the balloon. This is illustrated in Fig. 18, wherein balloon 240 is shown sucked into a blocking position at distal end 275 of central tube 230. This may result in preventing complete deflation of balloon 240.

To prevent this potential problem, a hole may be formed in the central tube wall as shown in Figs. 17a, 17b, and 19. As shown in Figs. 17a and 17b, hole 261 is formed so that inflation medium can enter and be withdrawn from a balloon surrounding the central tube 230. The inflation medium can pass both at the distal

end of the central tube 230 and laterally through hole 261. This prevents a deflation limitation or stoppage which could result at the distal end of central tube 230, as shown in Fig. 18. Fig. 19 shows a cross-sectional view of central tube 230 having hole 261 with balloon 240 and shroud 232 disposed therearound.

5 Fig. 20 illustrates an embodiment having a breathing tube 301 where inflation lumen 300 is disposed within the wall of breathing tube 301. In this embodiment, balloon 302 is shown disposed around breathing tube 301, and inflation lumen 300 is disposed radially offset from the central axis of breathing tube 301. Here, inflation lumen 300 extends along the entire length of breathing tube 301, and is blocked at its
10 distal end by glue 303. Alternatively, inflation lumen 300 could be formed so as not to continue all the way to the end of the breathing tube 301 (as shown in Fig. 1). The important aspect of inflation lumen 300 is that it not be open at the breathing tube's distal end.

To allow delivery of inflation medium to balloon 302, a hole 304 is provided
15 along inflation lumen 300. The hole could be formed from a number of different techniques. A preferred method of making the hole in this embodiment includes the use of a punch. The punch is a metal tube, with one end sharpened like a circular knife, which is inserted into the side of breathing tube 301 only far enough to create the hole 304. The use of a punch, instead of a conventionally drilled hole, helps
20 insure that a conventional drill does not continue into the breathing passageway and open a hole there during manufacture of the device.

An additional advantage to using the punch, instead of a conventional drill, is that, unlike a conventional drill, the punch cuts a clean hole and does not create loose material or shavings which could be difficult to remove from the device and could

cause a contamination hazard during later use of the device. By using the punch, the punched material is removed within the shaft of the punch and discarded.

The foregoing comprises a description of certain exemplary embodiments of
5 the present invention. The invention is not limited to these embodiments, however,
and the subjoined claims are intended to be construed to encompass all embodiments
of this invention, and equivalents and variants thereof, which may be made by those
skilled in the art without departing from the true spirit and scope of the essential
concepts disclosed and claimed herein.

10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60
61
62
63
64
65
66
67
68
69
70
71
72
73
74
75
76
77
78
79
80
81
82
83
84
85
86
87
88
89
90
91
92
93
94
95
96
97
98
99
100
101
102
103
104
105
106
107
108
109
110
111
112
113
114
115
116
117
118
119
120
121
122
123
124
125
126
127
128
129
130
131
132
133
134
135
136
137
138
139
140
141
142
143
144
145
146
147
148
149
150
151
152
153
154
155
156
157
158
159
160
161
162
163
164
165
166
167
168
169
170
171
172
173
174
175
176
177
178
179
180
181
182
183
184
185
186
187
188
189
190
191
192
193
194
195
196
197
198
199
200
201
202
203
204
205
206
207
208
209
210
211
212
213
214
215
216
217
218
219
220
221
222
223
224
225
226
227
228
229
230
231
232
233
234
235
236
237
238
239
240
241
242
243
244
245
246
247
248
249
250
251
252
253
254
255
256
257
258
259
260
261
262
263
264
265
266
267
268
269
270
271
272
273
274
275
276
277
278
279
280
281
282
283
284
285
286
287
288
289
290
291
292
293
294
295
296
297
298
299
300
301
302
303
304
305
306
307
308
309
310
311
312
313
314
315
316
317
318
319
320
321
322
323
324
325
326
327
328
329
330
331
332
333
334
335
336
337
338
339
340
341
342
343
344
345
346
347
348
349
350
351
352
353
354
355
356
357
358
359
360
361
362
363
364
365
366
367
368
369
370
371
372
373
374
375
376
377
378
379
380
381
382
383
384
385
386
387
388
389
390
391
392
393
394
395
396
397
398
399
400
401
402
403
404
405
406
407
408
409
410
411
412
413
414
415
416
417
418
419
420
421
422
423
424
425
426
427
428
429
430
431
432
433
434
435
436
437
438
439
440
441
442
443
444
445
446
447
448
449
450
451
452
453
454
455
456
457
458
459
460
461
462
463
464
465
466
467
468
469
470
471
472
473
474
475
476
477
478
479
480
481
482
483
484
485
486
487
488
489
490
491
492
493
494
495
496
497
498
499
500
501
502
503
504
505
506
507
508
509
510
511
512
513
514
515
516
517
518
519
520
521
522
523
524
525
526
527
528
529
530
531
532
533
534
535
536
537
538
539
540
541
542
543
544
545
546
547
548
549
550
551
552
553
554
555
556
557
558
559
560
561
562
563
564
565
566
567
568
569
570
571
572
573
574
575
576
577
578
579
580
581
582
583
584
585
586
587
588
589
590
591
592
593
594
595
596
597
598
599
600
601
602
603
604
605
606
607
608
609
610
611
612
613
614
615
616
617
618
619
620
621
622
623
624
625
626
627
628
629
630
631
632
633
634
635
636
637
638
639
640
641
642
643
644
645
646
647
648
649
650
651
652
653
654
655
656
657
658
659
660
661
662
663
664
665
666
667
668
669
670
671
672
673
674
675
676
677
678
679
680
681
682
683
684
685
686
687
688
689
690
691
692
693
694
695
696
697
698
699
700
701
702
703
704
705
706
707
708
709
710
711
712
713
714
715
716
717
718
719
720
721
722
723
724
725
726
727
728
729
730
731
732
733
734
735
736
737
738
739
740
741
742
743
744
745
746
747
748
749
750
751
752
753
754
755
756
757
758
759
760
761
762
763
764
765
766
767
768
769
770
771
772
773
774
775
776
777
778
779
780
781
782
783
784
785
786
787
788
789
790
791
792
793
794
795
796
797
798
799
800
801
802
803
804
805
806
807
808
809
810
811
812
813
814
815
816
817
818
819
820
821
822
823
824
825
826
827
828
829
830
831
832
833
834
835
836
837
838
839
840
841
842
843
844
845
846
847
848
849
850
851
852
853
854
855
856
857
858
859
860
861
862
863
864
865
866
867
868
869
870
871
872
873
874
875
876
877
878
879
880
881
882
883
884
885
886
887
888
889
890
891
892
893
894
895
896
897
898
899
900
901
902
903
904
905
906
907
908
909
910
911
912
913
914
915
916
917
918
919
920
921
922
923
924
925
926
927
928
929
930
931
932
933
934
935
936
937
938
939
940
941
942
943
944
945
946
947
948
949
950
951
952
953
954
955
956
957
958
959
960
961
962
963
964
965
966
967
968
969
970
971
972
973
974
975
976
977
978
979
980
981
982
983
984
985
986
987
988
989
990
991
992
993
994
995
996
997
998
999
1000
1001
1002
1003
1004
1005
1006
1007
1008
1009
1010
1011
1012
1013
1014
1015
1016
1017
1018
1019
1020
1021
1022
1023
1024
1025
1026
1027
1028
1029
1030
1031
1032
1033
1034
1035
1036
1037
1038
1039
1040
1041
1042
1043
1044
1045
1046
1047
1048
1049
1050
1051
1052
1053
1054
1055
1056
1057
1058
1059
1060
1061
1062
1063
1064
1065
1066
1067
1068
1069
1070
1071
1072
1073
1074
1075
1076
1077
1078
1079
1080
1081
1082
1083
1084
1085
1086
1087
1088
1089
1090
1091
1092
1093
1094
1095
1096
1097
1098
1099
1100
1101
1102
1103
1104
1105
1106
1107
1108
1109
1110
1111
1112
1113
1114
1115
1116
1117
1118
1119
1120
1121
1122
1123
1124
1125
1126
1127
1128
1129
1130
1131
1132
1133
1134
1135
1136
1137
1138
1139
1140
1141
1142
1143
1144
1145
1146
1147
1148
1149
1150
1151
1152
1153
1154
1155
1156
1157
1158
1159
1160
1161
1162
1163
1164
1165
1166
1167
1168
1169
1170
1171
1172
1173
1174
1175
1176
1177
1178
1179
1180
1181
1182
1183
1184
1185
1186
1187
1188
1189
1190
1191
1192
1193
1194
1195
1196
1197
1198
1199
1200
1201
1202
1203
1204
1205
1206
1207
1208
1209
1210
1211
1212
1213
1214
1215
1216
1217
1218
1219
1220
1221
1222
1223
1224
1225
1226
1227
1228
1229
1230
1231
1232
1233
1234
1235
1236
1237
1238
1239
1240
1241
1242
1243
1244
1245
1246
1247
1248
1249
1250
1251
1252
1253
1254
1255
1256
1257
1258
1259
1260
1261
1262
1263
1264
1265
1266
1267
1268
1269
1270
1271
1272
1273
1274
1275
1276
1277
1278
1279
1280
1281
1282
1283
1284
1285
1286
1287
1288
1289
1290
1291
1292
1293
1294
1295
1296
1297
1298
1299
1300
1301
1302
1303
1304
1305
1306
1307
1308
1309
1310
1311
1312
1313
1314
1315
1316
1317
1318
1319
1320
1321
1322
1323
1324
1325
1326
1327
1328
1329
1330
1331
1332
1333
1334
1335
1336
1337
1338
1339
1340
1341
1342
1343
1344
1345
1346
1347
1348
1349
1350
1351
1352
1353
1354
1355
1356
1357
1358
1359
1360
1361
1362
1363
1364
1365
1366
1367
1368
1369
1370
1371
1372
1373
1374
1375
1376
1377
1378
1379
1380
1381
1382
1383
1384
1385
1386
1387
1388
1389
1390
1391
1392
1393
1394
1395
1396
1397
1398
1399
1400
1401
1402
1403
1404
1405
1406
1407
1408
1409
1410
1411
1412
1413
1414
1415
1416
1417
1418
1419
1420
1421
1422
1423
1424
1425
1426
1427
1428
1429
1430
1431
1432
1433
1434
1435
1436
1437
1438
1439
1440
1441
1442
1443
1444
1445
1446
1447
1448
1449
1450
1451
1452
1453
1454
1455
1456
1457
1458
1459
1460
1461
1462
1463
1464
1465
1466
1467
1468
1469
1470
1471
1472
1473
1474
1475
1476
1477
1478
1479
1480
1481
1482
1483
1484
1485
1486
1487
1488
1489
1490
1491
1492
1493
1494
1495
1496
1497
1498
1499
1500
1501
1502
1503
1504
1505
1506
1507
1508
1509
1510
1511
1512
1513
1514
1515
1516
1517
1518
1519
1520
1521
1522
1523
1524
1525
1526
1527
1528
1529
1530
1531
1532
1533
1534
1535
1536
1537
1538
1539
1540
1541
1542
1543
1544
1545
1546
1547
1548
1549
1550
1551
1552
1553
1554
1555
1556
1557
1558
1559
1560
1561
1562
1563
1564
1565
1566
1567
1568
1569
1570
1571
1572
1573
1574
1575
1576
1577
1578
1579
1580
1581
1582
1583
1584
1585
1586
1587
1588
1589
1590
1591
1592
1593
1594
1595
1596
1597
1598
1599
1600
1601
1602
1603
1604
1605
1606
1607
1608
1609
1610
1611
1612
1613
1614
1615
1616
1617
1618
1619
1620
1621
1622
1623
1624
1625
1626
1627
1628
1629
1630
1631
1632
1633
1634
1635
1636
1637
1638
1639
1640
1641
1642
1643
1644
1645
1646
1647
1648
1649
1650
1651
1652
1653
1654
1655
1656
1657
1658
1659
1660
1661
1662
1663
1664
1665
1666
1667
1668
1669
1670
1671
1672
1673
1674
1675
1676
1677
1678
1679
1680
1681
1682
1683
1684
1685
1686
1687
1688
1689
1690
1691
1692
1693
1694
1695
1696
1697
1698
1699
1700
1701
1702
1703
1704
1705
1706
1707
1708
1709
1710
1711
1712
1713
1714
1715
1716
1717
1718
1719
1720
1721
1722
1723
1724
1725
1726
1727
1728
1729
1730
1731
1732
1733
1734
1735
1736
1737
1738
1739
1740
1741
1742
1743
1744
1745
1746
1747
1748
1749
1750
1751
1752
1753
1754
1755
1756
1757
1758
1759
1760
1761
1762
1763
1764
1765
1766
1767
1768
1769
1770
1771
1772
1773
1774
1775
1776
1777
1778
1779
1780
1781
1782
1783
1784
1785
1786
1787
1788
1789
1790
1791
1792
1793
1794
1795
1796
1797
1798
1799
1800
1801
1802
1803
1804
1805
1806
1807
1808
1809
1810
1811
1812
1813
1814
1815
1816
1817
1818
1819
1820
1821
1822
1823
1824
1825
1826
1827
1828
1829
1830
1831
1832
1833
1834
1835
1836
1837
1838
1839
1840
1841
1842
1843
1844
1845
1846
1847
1848
1849
1850
1851
1852
1853
1854
1855
1856
1857
1858
1859
1860
1861
1862
1863
1864
1865
1866
1867
1868
1869
1870
1871
1872
1873
1874
1875
1876
1877
1878
1879
1880
1881
1882
1883
1884
1885
1886
1887
1888
1889
1890
1891
1892
1893
1894
1895
1896
1897
1898
1899
1900
1901
1902
1903
1904
1905
1906
1907
1908
1909
1910
1911
1912
1913
1914
1915
1916
1917
1918
1919
1920
1921
1922
1923
1924
1925
1926
1927
1928
1929
1930
1931
1932
1933
1934
1935
1936
1937
1938
1939
1940
1941
1942
1943
1944
1945
1946
1947
1948
1949
1950
1951
1952
1953
1954
1955
1956
1957
1958
1959
1960
1961
1962
1963
1964
1965
1966
1967
1968
1969
1970
1971
1972
1973
1974
1975
1976
1977
1978
1979
1980
1981
1982
1983
1984
1985
1986
1987
1988
1989
1990
1991
1992
1993
1994
1995
1996
1997
1998
1999
2000
2001
2002
2003
2004
2005
2006
2007
2008
2009
2010
2011
2012
2013
2014
2015
2016
2017
2018
2019
2020
2021
2022
2023
2024
2025
2026
2027
2028
2029
2030
2031
2032
2033
2034
2035
2036
2037
2038
2039
2040
2041
2042
2043
2044
2045
2046
2047
2048
2049
2050
2051
2052
2053
2054
2055
2056
2057
2058
2059
2060
2061
2062
2063
2064
2065
2066
2067
2068
2069
2070
2071
2072
2073
2074
2075
2076
2077
2078
2079
2080
2081
2082
2083
2084
2085
2086
2087
2088
2089
2090
2091
2092
2093
2094
2095
2096
2097
2098
2099
2100
2101
2102
2103
2104
2105
2106
2107
2108
2109
2110
2111
2112
2113
2114
2115
2116
2117
2118
2119
2120
2121
2122
2123
2124
2125
2126
2127
2128
2129
2130
2131
2132
2133
2134
2135
2136
2137
2138
2139
2140
2141
2142
2143
2144
2145
2146
2147
2148
2149
2150
2151
2152
2153
2154
2155
2156
2157
2158
2159
2160
2161
2162
2163
2164
2165
2166
2167
2168
2169
2170
2171
2172
2173
2174
2175
2176
2177
2178
2179
2180
2181
2182
2183
2184
2185
2186
2187
2188
2189
2190
2191
2192
2193
2194
2195
2196
2197
2198
2199
2200
2201
2202
2203
2204
2205
2206
2207